

Comparative Study to Evaluate the Effect of Tamsulosin and Solifenacin on DJ Stent Related Symptoms

Md Masud Rana^{1*}, Md Shaheen Reza², Md Tanuwar Islam Chowdhury³, Md Mostakim Maoya⁴, Md Asaduzzaman⁵, Munshi Akid Mostofa⁶, Md Abu Sayed⁷ and Mohammad Ali Arafat⁸

¹Assistant Professor, Department of Urology, Bangladesh Medical College and Hospital, Dhaka, Bangladesh

²Assistant Professor, Department of Urology, Sheikh Hasina Medical College and Hospital, Tangail, Bangladesh

³Assistant Registrar, Department of Urology, Shaheed Suhrawardy Medical College and Hospital, Dhaka, Bangladesh

⁴Specialist, Department of Urology, Evercare Hospital, Dhaka, Bangladesh

⁵Assistant Registrar, Department of Urology, Rajshahi Medical College Hospital, Rajshahi, Bangladesh

⁶Assistant Registrar, Department of Urology, National Institute of Cancer Research and Hospital, Dhaka, Bangladesh

⁷Assistant Professor, Department of Urology, Kidney Foundation Hospital and Research Institute, Dhaka, Bangladesh

⁸Junior Consultant, Department of Urology, Bangladesh Medical College and Hospital, Dhaka, Bangladesh

***Corresponding Author:** Md Masud Rana, Assistant Professor, Department of Urology, Bangladesh Medical College and Hospital, Dhaka, Bangladesh.

DOI: 10.31080/ASOL.2023.05.0553

Received: March 13, 2023

Published: March 27, 2023

© All rights are reserved by **Md Masud Rana, et al.**

Abstract

Background: On patient quality of life, stent-associated symptoms can have a significant impact. Related to indwelling ureteral stents, hematuria, urgency, frequency, dysuria, and both bladder and flank pain are the most prevalent symptoms. Among them low back pain and irritative lower urinary tract symptoms and are more frequent. Because of its importance stent is being kept in situ with varieties of medication despite the stent related symptoms. To relief these symptoms like Tamsulosin, Solifenacin, Alphazosin etc., several alpha-adrenergic blocker and antimuscarinic drugs are used. Tamsulosin and Solifenacin both are not costly as use daily single dose. So combination of Tamsulosin and Solifenacin cost effective and may act as a reliever of stent related symptoms also.

Objectives: To evaluate the effect of Tamsulosin and Solifenacin in relieving DJ stent related symptoms.

Methodology: This prospective quasi experimental study was performed from November 2016 to April 2018. Patients who placed DJ stent after endoscopic stone management in the Department of Urology, Dhaka Medical College and Hospital recruited as study population. A total of 47 patients who were stented following ureteroscopic lithotripsy were included, allocated purposively into two groups. Group A (Tamsulosin) 24 and and Group B (Solifenacin) 23 patients were selected by purposive sampling technique according to inclusion and exclusion criteria for the study.

Results: In the current study, the mean age of the patients was 39.08(\pm 8.798) and 38.84(\pm 11.063) in group A and group B respectively. Male patients were leading in both groups. Total IPSS, irritative subgroup of IPSS, QOL score and VAS on T1 assessment done on 3rd postoperative day were evaluated in both the groups and no statistically significant difference ($P > 0.05$) in all scores were noted. In the study, the mean value of total IPSS, irritative subgroup of IPSS and QOLS was significantly improved in group-A in comparison to that of group B, 6.28, 3.2, 2.4 and 7.40, 4.04, 2.8 respectively ($P < 0.05$). The intensity of stent-related flank pain in group A was significantly lower than in the group B (2.36 compared with 2.64, $P < 0.05$).

Conclusion: This study was aimed to compare the outcomes of Tamsulosin and Solifenacin to relieve stent related symptoms. We conclude that Tamsulosin is more effective than Solifenacin in this regard.

Keywords: Endourological Procedures; Double-J Ureteral Stent; Tamsulosin; Solifenacin

Introduction

Endourological procedures are commonly performed worldwide. Since The Double-J ureteral stent has been an indispensable tool in the urologist's surgical armamentarium [1]. But its first description in 1967 by Zimskind., *et al.* [2], The Double-J or pigtail stent is a catheter or tube placed within the ureteral lumen in a retrograde or ante grade fashion in order to maintain its patency by definition [3]. In a wide range of situations where urinary drainage is needed, ureteral stents play a major role. Urgent indications include relief of benign or malignant obstruction. Other indications are: before or after ESWL to facilitate stone passage; per operative identification of ureter; perioperative placement like after ureteroscopic stone removal or any ureteroscopic intervention to maintain luminal calibre; management of urinary leakage- leak from trauma or surgery, leak due to ureteric fistula etc. [4]. Although ureteric JJ stents have been widely used in Urology for many decades and their placement is considered a routine procedure, they are associated with significant morbidity and a negative impact on patient's quality of life. Stent discomfort can vary from one patient to another but is believed to affect over 80% of patients in an idiosyncratic manner [5] Several studies in literature describe the symptoms related to ureteral stents and their respective estimated incidence: incomplete emptying (76%), urgency (57-60%), frequency (50-60%), dysuria (40%), flank pain (19-32%), suprapubic pain (30%) and hematuria (25%) [6-11]. Joshi., *et al.* (2002) [5] first reported how to objectively evaluate the symptomatology associated with stents. They consequently assessed the prevalence and bother of various urinary tract symptoms caused by indwelling ureteral catheters using validated questionnaires, like (International Prostatic Symptoms Score (IPSS),

Bristol Female Lower Urinary Tract Symptoms questionnaire - BFLUTS), International Continence Society male questionnaire, Quality of Life questionnaires. In order to better orientation, clinical decision making and practice they later developed and validated a questionnaire to specifically address this purpose, the 'Ureteral Stent Symptom Questionnaire (USSQ)' consisting of 38 items examining 6 sections: pain, voiding symptoms, work performance, sexual matters, overall general health, and additional problems [12]. Some aetiologies have been hypothesized for these complications includes mechanical irritation of the bladder trigone, urine renal reflux from bladder resulting obstruction, bacterial colonization of stent, stent positioning as well as size of stent and design. Strategies for managing stent complications include accurate stent indications, pre stenting manoeuvres, stent length, design and use of medications [3]. Strategies for managing SRS include accurate stent indications, pre stenting manoeuvres, adequate stent length and position, changing design of stents and use of medications [13]. Many efforts have been made to develop and test newer stents with specialized surface coating supposed to have a lower potential for inducing symptoms but they remain to be seen in general clinical use, mainly because of their high production costs and insubstantial clinical effects in the trials carried out so far [14]. Davenport and colleagues did not found any significant improvement of patients' quality of life following using a new design of Double-J stent [15]. Most commonly used method for alleviating SRS is to use of medications. According to the report of [16], alpha- adrenoreceptor blocker such as Tamsulosin was used and proved to be effective in some recent studies. The rationale to use alpha-blocker is based on the similarity of SRS to benign prostatic hyperplasia-related lower

urinary tract symptoms (LUTS). The pharmacological effect of this group of drugs is ureteral smooth muscle relaxation and trigonal inhibition [17]. Anticholinergic agents are also widely used to mitigate SRS. Anticholinergic such as Solifenacin overcome SRS by inhibiting involuntary contraction of the bladder that is produced due to presence of Double-J stent within the bladder [18]. In Dhaka Medical College Hospital, placement of Double-J stent following different emergency and routine urological procedures and stent related morbidity is very common phenomena. But, as per my knowledge, no published study has been found in Bangladesh to mitigate this problem. This study was intended to evaluate the effect of Tamsulosin and Solifenacin in relieving Double-J stent related symptoms in our center.

Objectives

General objective

To evaluate the effect of Tamsulosin and Solifenacin in relieving DJ stent related symptoms.

Specific objectives

- International Prostate Symptom Score (IPSS) following administration of Tamsulosin and Solifenacin in patients with DJ stent *in situ*.
- To compare the quality of life score (QOLS).
- To compare flank pain following administration of Tamsulosin and Solifenacin in patients with DJ stent *in situ*.

Inclusion criteria

Age between 18-40 years. Patients who were stented following ureteroscopic lithotripsy.

Methodology

For the study, 50 patients of urinary stone disease who were planned for endoscopic management were selected and then allocated into two groups with equal number of distribution by purposive sampling technique according to inclusion and exclusion criteria for the study. The study patients underwent URS pneumolithotripsy. URS was done with 8.5 Fr ureteroscope (Karl-Storz). In each cases pneumatic lithotripter were used. 6 Fr and 26 cm long DJ stent composed of polyurethane material was put in every cases under fluoroscopic guidance. Postoperative X-ray KUB

was done in all patients to rule out residual stone fragment and position of the stent. Foleys catheter was removed on 1st post-op day (POD). Patients were discharged on 3rd POD with an advice to take Tab. Levofloxacin, 500mg, OD for 7 days. In addition to this, the patients of Group-A and those of Group-B were advised to take Cap. Tamsulosin 0.4 mg, once a day at bed time and Tab. Solifenacin 5 mg, once in the morning, respectively, every day up to stent removal. DJ stent was removed after 3 weeks. On postoperative day 3 (T₁ assessment) and on the day of stent removal (T₂ assessment), each patient completed a written International Prostate Symptom Score (IPSS) and visual analogue pain scale (VAS) questionnaires. The IPSS was divided into the total score and irritative symptom sub score.

Ethical consideration

The study was approved by Ethical Clearance Committee of Dhaka Medical College.

Statistical analysis of data

All the collected data were compiled. Percentages were calculated to find out proportion of the findings. Further Statistical analyses of the results were obtained by using Microsoft Xcel, 2010 (Microsoft Corporation, Washington, U.S.) and web based computer software – Graph Pad Software, 2017 (Graph Pad Software, Inc., USA). Quantitative data were expressed as mean and standard deviation and compared by Student “t” test. Qualitative data were expressed as frequency and percentage, compared by Fisher’s exact test. A probability value (p) of less than 0.05 was considered to indicate statistical significance. The summarized findings were then presented in the form of tables and graphs.

Results

Age	Group		P- value
	Group-A (Tamsulosin) n(24)	Group-B (Solifenasin) n(23)	
Mean ± SD	39.08 ± 8.798	38.84± 11.063	0.9346

Table 1: Distribution of the patients according to age (N = 47).

Table 1 showed that the mean age (\pm SD) in group-A and Group-B is 39.08(\pm 8.798) and 38.84(\pm 11.063) respectively. The difference of mean (\pm SD) age of the two groups was not statistically significant ($p = 0.9346$).

Sex	Group	
	Group-A (Tamsulosin) n (%)	Group-B (Solifenasin) n (%)
Male	18(75.00)	18(78.26)
Female	6(25.00)	5(21.74)

Table 2: Distribution of the patients according to sex (N = 47).

Table 2 showed distribution of patients according to sex. Male patients were predominant in both groups.

Figure 1: Sex Wise Patients Distribution (N = 47).

Observations	Group		P- value
	Group-A (Tamsulosin) Mean \pm SD	Group-B (Solifenasin) Mean \pm SD	
Total IPSS	10.72 \pm 2.716	09.76 \pm 2.521	0.2008
Irritative subgroup of IPSS	07.48 \pm 1.594	06.72 \pm 1.989	0.2774
QOL score	03.60 \pm 1.080	03.52 \pm 0.962	0.7833
VAS	04.08 \pm 1.222	03.96 \pm 1.171	0.7765

Table 3: Distribution of the patients according to total IPSS, irritative subgroup of IPSS, QOL score and VAS (T1 Assessment).

Table 3 showed no statistically significant difference ($P > 0.05$) in all evaluated scores in between Group-A and Group-B.

Figure 2: Patients Total IPSS, irritative subgroup of IPSS, QOL score and VAS (T1 assessment).

Figure 3: Distribution of α 1-adrenergic receptors in the lower urinary tract (McNicholas, Speakman and Kirby, 2016).

Figure 4: Distribution of autonomic receptor in bladder and proximal urethra.

Link: <https://musculoskeletalkey.com/storage-and-emptying-disorders-of-the-bladder/>

Total IPSS	Group		P-value
	Group-A (Tamsulosin)	Group-B (Solifenasin)	
Mean ± SD	6.28 ± 1.594	7.40 ± 1.979	0.0324

Table 4: Distribution of the patients according to total IPSS (T2 assessment).

Table 4 showed statistically significant difference ($P < 0.05$) in T2 assessment of total IPSS in between group A and group B.

Irritative subgroup of IPSS	Group		P- value
	Group-A (Tamsulosin)	Group-B (Solifenasin)	
Mean ± SD	3.24 ± 1.163	4.04 ± 1.247	0.0184

Table 5: Distribution of the patients according to irritative subgroup of IPSS (T2 assessment).

Table 5 shows statistically significant difference ($P < 0.05$) in T2 assessment of irritative subgroup of IPSS in between group A and group B.

QOLS	Groups		P-value
	Group-A (Tamsulosin)	Group-B (Solifenasin)	
Mean ± SD	2.4 ± 0.577	2.8 ± 0.942	0.0179

Table 6: Distribution of the patients according to QOLS (T2 assessment).

Table 6 shows statistically significant difference ($P < 0.05$) in T2 assessment of QOLS in between Group-A and Group-B.

Total IPSS	Groups		P- value
	Group-A (Tamsulosin)	Group-B (Solifenasin)	
Mean ± SD	2.64 ± 0.075	2.36 ± 0.907	0.0257

Table 7: Distribution of the patients according to VAS (T2 assessment).

Table 7 showed statistically significant difference ($P < 0.05$) in T2 assessment of VAS in between group-A and group-B.

Discussion

This Quassi experimental study was conducted in the Department of Urology, Dhaka Medical College Hospital, during the period of November 2016 to April 2018. For the study, 50 patients of urinary stone disease who underwent endoscopic management followed by DJ stenting were selected and then allocated into two groups: Group-A and Group-B and were advised to take Cap. Tamsulosin 0.4 mg and Tab. Solifenacin 5 mg respectively. In this study, the performance of the aforementioned drugs was compared in terms of their ability of improving stent related symptoms. The result of this study suggests that Tamsulosin performed better than Solifenacin. In the current study, the mean age of the patients was 39.08(± 8.798) and 38.84(±11.063) in Group-A and Group-B respectively. The difference of mean age of the two groups was not statistically significant ($p > 0.05$). Male patients were predominant in both groups. Total IPSS, irritative subgroup of IPSS, QOL score and VAS on T1 assessment done on 3rd postoperative day were evaluated in both the groups and no statistically significant difference ($p > 0.05$) in all scores were noted. These findings allow potentially meaningful comparisons between the groups. In the current study, the total IPSS, irritative subgroup of IPSS and QOLS was significantly improved in Group-A in comparison to that of Group-B. Total IPSS, QOLS and irritative subgroup of IPSS of Group-A and Group-B was 6.28, 3.2, 2.4 and 7.40, 4.04, 2.8 respectively ($P < 0.05$). Like our study, Shalaby, *et al.* (2013) [19] found poor performance of Solifenacin in relieving stent-related symptoms in comparison to Tamsulosin. He., *et al.* (2015) [11] found that α -blockers significantly decreased the mean urinary symptom score in their study. On the contrary, ELNahas and colleagues (2017) [16] showed that solifenacin was more effective than tamsulosin in relieving ureteral stent related symptoms as there was significant improvement in total USSQ score in their study. This contradictory result may be due to the difference in the method of evaluation of stent symptoms. We used IPSS, while most other researchers used the USSQ score. The intensity of stent-related flank pain in Group-A was significantly lower than in the Group-B (2.36 compared with 2.64, $P < 0.05$). The pathophysiology of stent-related flank pain is not completely understood. It is thought to be a result of urine reflux from the bladder to the kidney

especially with the increased pressure created during voiding. Tamsulosin occupies α -adrenergic receptors in the distal part of the ureter, bladder trigone and prostatic urethra. It decreases bladder outlet resistance and voiding pressure, and, therefore, potentially reduces the incidence of urine reflux and subsequent flank pain [20]. Zhou, *et al.* (2015) [21] in a meta-analysis, having a high statistical value, stated that there were statistically significant differences in VAS score ($P < 0.00001$) in favour of the α -blocker group. The study included a total of 13 articles and 1408 patients. Shalaby, *et al.* (2013) [19] found statistically significant difference in VAS scores in favour of Tamsulosin group ($P = 0.00$). Pawar and colleagues (2016) [20] also concluded with same result. For many patient's stent symptoms account for most of the morbidity associated with ureteroscopy. Many efforts have been made to mitigate this problem. In this study, we tried pharmacological means with Tamsulosin and Solifenacin. Our data suggests that Tamsulosin is more effective than Solifenacin in reducing stent related symptoms.

Limitations of the Study

Sample size was small, so it might not reflect the actual result of the study. It was a single centered study. Sampling technique was purposive. Blinding was not possible. Other stent related symptoms like haematuria, infection, sexual dysfunction was not considered.

Conclusion

Ureteral stent discomfort is a significant postoperative problem for many patients. For lower urinary tract symptoms and pain, patients often experience bothersome which impair daily activities. We compared an alpha-blocker Tamsulosin with an anticholinergic Solifenacin to alleviate the problem. This study was aimed to compare the outcomes of Tamsulosin and Solifenacin to relieve stent related symptoms. We conclude that Tamsulosin is more effective than Solifenacin in this regard.

Bibliography

1. Singh I. "Indwelling JJ ureteral stents - a current perspective and review of literature". *Indian Journal of Surgery* 65 (2003): 405-412.
2. Zimskind PD., *et al.* "Clinical use of long-term indwelling silicone rubber ureteral splints inserted cystoscopically". *Journal of Urology* 97 (1967): 840-844.
3. Miyaoka R and Monga M U. "Ureteral stent discomfort: Etiology and management". *Indian Journal of Urology* 25.4 (2009): 455-460.
4. Knudsen BE., *et al.* "Stenting after ureteroscopy: pros and cons". *Urologic Clinics of North America* 31 (2004): 173-80.
5. Joshi HB., *et al.* "Characterization of urinary symptoms in patients with ureteral stents". *Urology* 59 (2002): 511-519.
6. Byrne RR., *et al.* "Routine ureteral stenting is not necessary after ureteroscopy and ureteropyeloscopy: a randomized trial". *Journal of Endourology* 16 (2002): 9-13.
7. Hao P., *et al.* "Clinical evaluation of double-pigtail in patients with upper urinary tract diseases: report of 2685 cases". *Journal of Endourology* 22 (2008): 65-70.
8. Thomas R. "Indwelling ureteral stents: Impact of material and shape on patient comfort". *Journal of Endourology* 7 (1993): 137-140.
9. Sur RL., *et al.* "Efficacy of intravesical ropivacaine injection on urinary symptoms following ureteral stenting: a randomized, controlled study". *Journal of Endourology* 22 (2008): 473-478.
10. Rane A., *et al.* "Have stent-related symptoms anything to do with placement technique?". *Journal of Endourology* 15 (2001): 741-744.
11. Smedley FH., *et al.* "168 Double J (pigtail) ureteric catheter insertions: A retrospective review". *Annals of The Royal College of Surgeons of England Home* 70 (1988): 377-379.
12. Joshi HB., *et al.* "Ureteral stent symptom questionnaire: development and validation of a multidimensional quality of life measure". *Journal of Urology* 169 (2003): 1060-1064.
13. Sivalingam S., *et al.* "Does Combination Therapy with Tamsulosin and Tolterodine Improve Ureteral Stent Discomfort Compared with Tamsulosin Alone? A Double-Blind, Randomized, Controlled Trial". *Journal of Urology* 195 (2016): 385-390.
14. Betschart P., *et al.* "Prevention and treatment of symptoms associated with indwelling ureteral stents: A systematic review". *International Journal of Urology* 24.4 (2017): 250-259.
15. Davenport R., *et al.* "Functional definition and characterization of acute traumatic coagulopathy". *Critical Care Medicine* 39.12 (2011): 2652-2658.

16. El-Nahas AR., *et al.* Department of Urology, Urology and Nephrology Center, Department of Radiology, Department of Clinical Pathology, Department of Microbiology, Department of Nephrology, Department of Molecular Biology Laboratory, Mansoura University, Mansoura, Egypt (2017).
17. He F., *et al.* "Efficacy of α -blocker in improving ureteral stent-related symptoms: a meta-analysis of both direct and indirect comparison". *Drug Design, Development and Therapy* 10 (2015): 1783-1793.
18. Lee YJ., *et al.* "Solifenacin improves Double-J stent- related symptoms in both genders following uncomplicated ureteroscopic lithotripsy". *Urolithiasis* 41 (2013): 247-53.
19. Shalaby E., *et al.* "Randomized controlled trial to compare the safety and efficacy of tamsulosin, solifenacin, and combination of both in treatment of Double-J stent-related lower urinary symptoms". *Advances in Urology* (2013): 1-6.
20. Pawar D., *et al.* "Comparative study to evaluate effect of tamsulosin and Solifenacin on DJ stent related symptoms". *IOSR Journal of Dental and Medical Sciences* 15.10 (2016): 34-37.
21. Zhou L., *et al.* "Effects of α -Blockers, Antimuscarinics, or Combination Therapy in Relieving Ureteral Stent-Related Symptoms: A Meta-Analysis". *Journal of Endourology* 29.6 (2015): 650-656.